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- 46. (New) The nucleic acid of claim 10, comprising the nucleic acid sequence as set forth as SEQ ID NO: 13.
  - 47. (New) A vector comprising the nucleic acid of claim 15.
- 48. (New) The method of claim 36, comprising detecting the hybridization in a prostate epithelial cell of a male.
- 49. (New) The method of claim 36, comprising detecting the hybridization in a breast cell of a female.
- 50. (New) A method of detecting cancer in a subject, comprising detecting the contacting of an antibody that specifically binds a protein having the amino acid sequence as set forth as SEQ ID NO: 14, or a variant thereof having a conservative substitution in a sample from the subject, whereby detection of the binding indicates that the subject has cancer.
- 51. (New) The method of claim 36, wherein the subject is a male and the cell is a prostate epithelial cell.
- 52. (New) The method of claim 36, wherein the subject is a female and the cell is a breast cell.
  - (New) The method of claim 51, wherein the sample comprises a lymph node cell.
- 54. (New) The method of claim 51, wherein the sample comprises a breast biopsy cell.

#### REMARKS

Claims 1-44 were pending in the instant application. By this amendment, claims 1-6, 10, 15-20, 24-36, 40-44 are amended, claims 7-9, 11-14 and 21-23 are canceled, claims 37-39 are reiterated, and claims 45-54 are added. Therefore, after entry of this amendment, claims 1-6, 10,

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15-20, and 24-54 are now pending. No new matter is added. Examination of the patent application is respectfully requested.

### Amendments

No new matter has been added by these amendments. Support for the language of these amendments can be found throughout the specification, and specifically on the pages noted below:

Claim	Amendment	Support in Specification
1	Substantially purified	Pg. 18, lines 26-32
	SEQ ID NO: 14	Pg. 7, line 9
	Variant	Pg. 17, line 35
	Conservative substitution	Pg. 18, lines 14-25
2	Substantially purified	Pg. 18, lines 26-32
	SEQ ID NO: 14	Pg. 7, line 9
	Variant	Pg. 17, line 35
	Conservative substitution	Pg. 18, lines 14-25
3	Substantially purified	Pg. 18, lines 26-32
	SEQ ID NO: 14	Pg. 7, line 9
	Variant	Pg. 17, line 35
	Conservative substitution	Pg. 18, lines 14-25
4	Substantially purified	Pg. 18, lines 26-32
	SEQ ID NO: 14	Pg. 7, line 9
5	Substantially purified	Pg. 18, lines 26-32
	SEQ ID NO: 14	Pg. 7, line 9
6	Changed dependency to claim 1	Pg. 41 line 16-pg. 42, line 9
7	Canceled	,
8	Canceled	
9	Canceled	
10	Substantially purified	Pg. 18, lines 26-32
	Changed dependency to claim 1	Claim 1 as originally filed
11	Canceled	
12	Canceled	
13	Canceled	
14	Canceled	
15	Substantially purified	Pg. 18, lines 26-32
	Amendment of form	
16	Substantially purified	Pg. 18, lines 26-32
	Amendment of form	
	SEQ ID NO: 14	Pg. 7, line 9
	Variant	Pg. 17, line 35

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	Amendment of form SEQ ID NO: 14	Pg. 7, line 9
	Variant	Pg. 17, line 35
	Conservative substitution	Pg. 18, lines 14-25
18	Substantially purified	Pg. 18, lines 26-32
	SEQ ID NO: 14	Pg. 7, line 9.
19	Substantially purified	Pg. 18, lines 26-32
	SEQ ID NO: 14	Pg. 7, line 9
20	Specified that method is for eliciting	Pg. 28, line 1 to pg. 33, line 10
	immune response	
	Expression vector	Pg. 20, line 30 - 32
	Changed dependency to claim 1	Claim 1 as originally filed
	Substantially purified	Pg. 18, lines 26-32
	Thereby eliciting an immune response	Amendment of form
21	Canceled	÷ ,
22	Canceled	
23	Canceled	
24	Amendment of form	
25	Amendment of form	
26	At risk for developing	Specifying subject identity (pg. 28, lines 19-21)
27	Amendment of form	
	Sensitized with antigen presenting	Pg 31, lines 26-31
	cells pulsed with a polypeptide	- E -
	SEQ ID NO: 14	Pg. 7, line 9
	Variant	Pg. 17, line 35
00	Conservative substitution	Pg. 18, lines 14-25
28	Amendment of form	Pg. 7, line 9
αA		IPa / line u
29	SEQ ID NO: 14	
29	Variant	Pg. 17, line 35
	Variant Conservative substitution	
30	Variant Conservative substitution Amendment of form	Pg. 17, line 35 Pg. 18, lines 14-25
30	Variant Conservative substitution Amendment of form Substantially purified	Pg. 17, line 35 Pg. 18, lines 14-25 Pg. 18, lines 26-32
	Variant Conservative substitution Amendment of form Substantially purified SEQ ID NO: 13	Pg. 17, line 35 Pg. 18, lines 14-25  Pg. 18, lines 26-32 Pg. 7, line 6
30	Variant Conservative substitution Amendment of form Substantially purified SEQ ID NO: 13 Degenerate version	Pg. 17, line 35 Pg. 18, lines 14-25  Pg. 18, lines 26-32 Pg. 7, line 6 Pg. 20, line 6
30	Variant Conservative substitution Amendment of form Substantially purified SEQ ID NO: 13 Degenerate version Method of eliciting immune response	Pg. 17, line 35 Pg. 18, lines 14-25  Pg. 18, lines 26-32  Pg. 7, line 6 Pg. 20, line 6  Pg. 28, line 1 – pg 33, line 10
30	Variant Conservative substitution Amendment of form Substantially purified SEQ ID NO: 13 Degenerate version Method of eliciting immune response Composition	Pg. 17, line 35 Pg. 18, lines 14-25  Pg. 18, lines 26-32  Pg. 7, line 6 Pg. 20, line 6  Pg. 28, line 1 – pg 33, line 10 Pg. 28, lines 19-21
30 31 32	Variant Conservative substitution Amendment of form Substantially purified SEQ ID NO: 13 Degenerate version Method of eliciting immune response Composition Changed dependency to claim 15	Pg. 17, line 35 Pg. 18, lines 14-25  Pg. 18, lines 26-32  Pg. 7, line 6 Pg. 20, line 6  Pg. 28, line 1 – pg 33, line 10 Pg. 28, lines 19-21  Claim 15 as originally filed
30	Variant Conservative substitution Amendment of form Substantially purified SEQ ID NO: 13 Degenerate version Method of eliciting immune response Composition Changed dependency to claim 15 Method of eliciting an immune	Pg. 17, line 35 Pg. 18, lines 14-25  Pg. 18, lines 26-32  Pg. 7, line 6 Pg. 20, line 6  Pg. 28, line 1 – pg 33, line 10 Pg. 28, lines 19-21
30 31 32	Variant Conservative substitution Amendment of form Substantially purified SEQ ID NO: 13 Degenerate version Method of eliciting immune response Composition Changed dependency to claim 15 Method of eliciting an immune response comprising administering a	Pg. 17, line 35 Pg. 18, lines 14-25  Pg. 18, lines 26-32  Pg. 7, line 6 Pg. 20, line 6  Pg. 28, line 1 – pg 33, line 10 Pg. 28, lines 19-21  Claim 15 as originally filed  Pg. 28, line 1 – pg 33, line 10
30 31 32	Variant Conservative substitution Amendment of form Substantially purified SEQ ID NO: 13 Degenerate version Method of eliciting immune response Composition Changed dependency to claim 15 Method of eliciting an immune	Pg. 17, line 35 Pg. 18, lines 14-25  Pg. 18, lines 26-32  Pg. 7, line 6 Pg. 20, line 6  Pg. 28, line 1 – pg 33, line 10 Pg. 28, lines 19-21  Claim 15 as originally filed

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35	Cytotoxic T cells	Pg. 16, lines 11-12
36	In a subject	Pg. 40, lines 28-30, describing
		samples taken from a subject
	Detecting hybridization of a probe	Pg. 41, lines 1-4
•	Sample	Pg. 40, lines 28-30.
•	Polypeptide of claim 1	Claim 1 as originally filed
	Hybridization indicates cancer	Pg. 41, lines 5-6
37	Reiterated	
38	Reiterated	
39	Reiterated	
40	Amendment of form	
41	Hybridization is detected in a sample	Pg. 39, line 23 – pg. 41, line 14
	comprising a cell of the subject	
42	Hybridization is detected in a sample	Pg. 39, line 23 – pg. 41, line 14
	comprising a cell of the subject	
43	Polypeptide of claim 1	Claim 1 as originally filed
44	Protein comprising SEQ ID NO: 14	Pg. 7, line 9
	Nucleic acid of claim 10	Claim 10 as originally filed
	Nucleic acid of claim 10	Claim 10 as originally filed
	Operatively linked to a promoter	Pg. 20, line 16-24

## New claims

Claims 45-55 are added by this amendment. Support for these claims in the specification as filed may be found as follows:

Claim	Amendment	Support in Specification
45	Part of original claim 1, divided out	Claim 1 as originally filed
46	Part of original claim 10, divided out and substituting the sequence	Claim 10 as originally filed,
	identifier, SEQ ID NO: 13	Pg. 7, line 6
47	Part of original claim 15, divided out	Claim 15 as originally filed
48	Derivation of cell from subject and returning cell as active immunization	Page 27, lines 24-34 and claims 36 and 39 as originally filed
49	Method of detecting cancer in a female	Pg. 39, line 23 – pg. 41, line 14
50	Method of detecting cancer in a subject	Pg. 39, line 23 – pg. 41, line 14
51	Method of detecting cancer in a male	Pg. 39, line 23 – pg. 41, line 14
52	Method of detecting cancer in a female	Pg. 39, line 23 - pg. 41, line 14
53	Detection in a lymph node cell	Pg. 40, lines 28-30.

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1 64 Detection in a bound blower and	D. 40 1' 00 00
54   Detection in a breast biopsy cell	Pg. 40, lines 28-30,
	1 5. 10, mes 2d 30,

No new matter is added.

# **CONCLUSIONS**

If any minor matters remain to be discussed prior to examination, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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Ву

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# Marked-up Version of Amended Claims Pursuant to 37 C.F.R. §§ 1.121(b)-(c)

#### WHAT IS CLAIMED IS:

7. (Amended) [An isolated] A substantially purified polypeptide [comprising an amino acid sequence] comprising:

[selected from the group consisting of a TCR $\gamma$  Alternate Reading frame Protein ("TARP"),] (a) an amino acid sequence set forth as SEQ ID NO: 14, or a variant thereof having a conservative substitution;

- (b) an immunogenic fragment [thereof] of the protein comprising the amino acid sequence set forth as SEQ ID NO: 14, or variant thereof having a conservative substitution;[,]
- (c) a polypeptide with at least 90% sequence identity to [TARP] the amino acid sequence set forth as SEQ ID NO: 14 [and which] that is specifically recognized by an antibody [which] that specifically recognizes [TARP] the protein comprising the amino acid sequence set forth as SEQ ID NO: 14;[, and] or
- (d) a polypeptide [which] that has at least 90% sequence identity with [TARP] the amino acid set forth as SEQ ID NO: 14 and [which] that, when processed and presented in the context of Major Histocompatibility Complex molecules, activates T lymphocytes against cells [which] that express [TARP] the protein encoded by the amino acid sequence set forth as SEQ ID NO: 14.
- 8. (Amended) [An isolated] The substantially purified polypeptide of claim 1, wherein the polypeptide comprises [the sequence of TARP] the amino acid sequence set forth as SEQ ID NO: 14, or a variant thereof having a conservative substitution.
- 9. (Amended) [An isolated] The substantially purified polypeptide of claim 1, wherein the [polypetide] polypeptide comprises [the sequence of] an immunogenic fragment of [TARP] the amino acid sequence as set forth as SEQ ID NO: 14, or a variant thereof having a conservative substitution.

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- 10. (Amended) [An isolated] The substantially purified polypeptide of claim 1, [which] wherein the [polypetide] polypeptide has at least 90% sequence identity to [TARP] an amino acid sequence as set forth as SEO ID NO: 14 and is specifically recognized by an antibody [which] that specifically recognizes [TARP] the amino acid sequence as set forth as SEO ID NO: 14.
- (Amended) [An isolated] The substantially purified polypeptide of claim 1, [which] wherein the polypeptide has at least 90% sequence identity [with TARP] to the amino acid sequence as set forth as SEQ ID NO: 14 and [which] that, when processed and presented in the context of Major Histocompatibility Complex molecules, activates T lymphocytes against cells [which] that express [TARP] the protein encoded by the amino acid sequence as set forth as SEO ID NO: 14.
- 12. (Amended) A composition comprising a polypeptide of claim [2] 1 and a pharmaceutically acceptable carrier.

Please cancel claims 7-9.

10. (Amended) [An isolated,] A substantially purified recombinant nucleic acid molecule [comprising a nucleotide sequence encoding a polypeptide having the amino acid sequence of a TCRy Alternate Reading frame Protein ("TARP"), an immunogenic fragment thereof, a polypeptide with at least 90% sequence identity to TARP and which is specifically recognized by an antibody which specifically recognizes TARP, and a polypeptide which has at least 90% sequence identity with TARP and which, when processed and presented in the context of Major Histocompatibility Complex molecules, activates T lymphocytes against cells which express TARP] encoding the polypeptide of claim 1.

Please cancel claims 11-14.

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- 15. (Amended) The [isolated,] <u>substantially purified</u> recombinant nucleic acid molecule of claim 10 [which is an expression vector comprising a promoter], [operatively] <u>operably linked to a promoter</u> [the nucleotide sequence].
- 16. (Amended) The [isolated,] substantially purified recombinant nucleic acid molecule of claim 15, wherein [said] the nucleotide sequence encodes a polypeptide [having] comprising the amino acid sequence [of a TCRγ Alternate Reading frame Protein ("TARP")] as set forth as SEQ ID NO: 14, or a variant thereof having a conservative substitution.
- 17. (Amended) The [isolated,] <u>substantially purified</u> recombinant nucleic acid molecule of claim 15, wherein [said] <u>the</u> nucleotide sequence encodes a polypeptide [having] <u>comprising</u> the amino acid sequence of an immunogenic fragment of [TARP] <u>the protein comprising</u> the amino acid sequence as set forth as SEQ ID NO: 14, or variant thereof having a conservative substitution.
- 18. (Amended) The [isolated,] <u>substantially purified</u> recombinant nucleic acid molecule of claim 12, wherein [said] <u>the</u> nucleotide sequence encodes a polypeptide with at least 90% sequence identity to [TARP] <u>an amino acid sequence as set forth as SEQ ID NO: 14</u> and [which] <u>that</u> is specifically recognized by an antibody [which] <u>that</u> specifically recognizes [TARP] a protein comprising the amino acid sequence as set forth as SEQ ID NO: 14.
- 19. (Amended) The [isolated,] <u>substantially purified</u> recombinant nucleic acid of claim 12, wherein [said] <u>the</u> nucleotide sequence encodes a polypeptide [which] <u>that</u> has at least 90% sequence identity [with TARP] <u>to the amino acid sequence as set forth as SEQ ID NO: 14 and [which] that</u>, when processed and presented in the context of Major Histocompatibility Complex molecules, activates T lymphocytes against cells [which] <u>that</u> express [TARP] <u>the</u> amino acid sequence as set forth as SEQ ID NO: 14.
- 20. (Amended) A method for eliciting an immune response in a subject, comprising administering to a subject a composition [, which composition is selected from the group consisting of: an isolated polypeptide having the amino acid sequence of a TCRy Alternate

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Reading frame Protein ("TARP"), an immunogenic fragment thereof, a polypeptide with at least 90% sequence identity to TARP and which is specifically recognized by an antibody which specifically recognizes TARP, a polypeptide which has at least 90% sequence identity with TARP and which, when processed and presented in the context of Major Histocompatibility Complex molecules, activates T lymphocytes against cells which express TARP], comprising:

## (a) the polypeptide of claim 1;

- (b) [an isolated] a substantially purified nucleic acid encoding [one of these] the polypeptide[s] of claim 1 in an expression vector;
- (c)[,] an antigen presenting cell pulsed with a polypeptide comprising an epitope of [TARP,] the polypeptide of claim 1 [and cells sensitized in vitro to TARP], or an immunogenic fragment thereof, [a polypeptide with at least 90% sequence identity to TARP which is specifically recognized by an antibody which specifically recognizes TARP, or a polypeptide which has at least 90% sequence identity with TARP which, when processed and presented in the context of Major Histocompatibility Complex molecules, activates T lymphocytes against cells which express TARP.]

thereby eliciting an immune response in the subject.

Please cancel claims 21-23.

- 24. (Amended) The method of claim 20 wherein the [administration to a] subject [who suffers from] has prostate cancer.
- 25. (Amended) The method of claim 20, wherein the [administration is to a] subject [who suffers from] has breast cancer.
- 26. (Amended) The method of claim 20, wherein the [administration is to a female] subject [who has not been diagnosed with] is a female at risk for developing breast cancer.
- 27. (Amended) The method of claim 20 wherein the [administration] administered composition further comprises [sensitizing] CD8+ cells [in vitro to an epitope of a TARP protein and administering the sensitized cells to the subject] that are sensitized with antigen presenting

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cells pulsed with a polypeptide comprising an epitope of the protein having an amino acid sequence as set forth as SEQ ID NO: 14, or a variant thereof having a conservative substitution.

- 28. (Amended) The method of claim 20, further comprising co-administering to the subject an immune adjuvant [selected from] comprising a non-specific immune [adjuvants] adjuvant, a subcellular microbial [products] product and [fractions] fraction, a [haptens] hapten, an immunogenic [proteins] protein, an [immunomodulators] immunomodulator, an [interferons] interferon, a thymic [hormones] hormone [and], or a colony stimulating [factors] factor.
- 29. (Amended) The method of claim 20, comprising administering an antigen presenting cell pulsed with a polypeptide comprising an epitope of [TARP] the protein having an amino acid sequence as set forth as SEQ ID NO: 14, or a variant thereof having a conservative substitution.
- 30. (Amended) The method of claim 20 [comprising administering a], wherein the substantially purified nucleic acid [sequence encoding polypeptide comprising an epitope of TARP, which nucleic acid] is in a recombinant virus.
- 31. (Amended) The method of claim 20 [comprising administering a] wherein the nucleic acid has a sequence as set forth as SEQ ID NO: 13 or a degenerate version thereof. [encoding a polypeptide comprising an epitope of a TARP protein].
- 32. (Amended) [The] A method of [claim 20] eliciting an immune response, comprising administering [an expression vector that expresses a polypeptide] to a subject a composition, comprising [an epitope of a TARP protein, which expression vector is in] a recombinant bacterial cell comprising the nucleic acid molecule of claim 15.
- 33. (Amended) [The] A method of [claim 20] eliciting an immune response, comprising administering to a subject a composition, comprising [immunizing the subject with a expression vector that expresses a polypeptide comprising an epitope of a TARP protein, which

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expression vector is in] an autologous recombinant cell comprising the nucleic acid molecule of claim 15.

- 34. (Amended) The method of claim 27 wherein the CD8+ cells are [T<sub>C</sub> cells] evtotoxic T lymphocytess.
- 35. (Amended) The method of claim 34 wherein the [T<sub>C</sub> cells] cytotoxic T lymphocytes are tumor infiltrating lymphocytes.
- 36. (Amended) A method for detecting[, in a male, a prostate cell of epithelial origin, or, in a female,] a [breast] cancer in a subject [cell], comprising detecting in a [cell] sample from [said male or said female] the subject the hybridization of a probe specific for a nucleic acid [transcript encoding TARP, or detecting TARP produced by translation of the transcript] that encodes the polypeptide of claim 1, whereby [detection of the transcript or of the protein in a cell from said male identifies the cell as a prostate epithelial cell and whereby detection of the transcript or of the protein in a cell from said female identifies the cell as a breast] the hybridization of the probe to the nucleic acid indicates that the subject has cancer [cell].
  - 37. (Reiterated) The method of claim 36, comprising detecting the transcript.
  - 38. (Reiterated) The method of claim 36, comprising detecting the protein.
- 39. (Reiterated) The method of claim 36, comprising contacting RNA from the cell with a nucleic acid probe that specifically hybridizes to the transcript under hybridization conditions, and detecting hybridization.
  - 40. (Amended) The method of claim 36, comprising disrupting [said] the cell and contacting a portion of the cell contents with a chimeric molecule comprising a targeting moiety and a detectable label, wherein the targeting moiety specifically binds to the protein, and detecting the label bound to the protein.

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- 41. (Amended) The method of claim 36, wherein the [cell is taken from] hybridization is detected in a sample comprising a lymph node cell of the subject.
- 42. (Amended) The method of claim 36, wherein the [cell is taken from] hybridization is detected in a sample comprising a breast biopsy cell of the subject.
- 43. (Amended) An antibody that specifically binds to [an epitope of a TCRγ Alternate Reading frame Protein] the polypeptide of claim 1.
- 44. (Amended) A method of modulating levels of [TARP] a protein comprising the amino acid sequence as set forth as SEQ ID NO: 14 in a cell, [said] comprising introducing into [said] the cell a composition [selected from the group consisting of] comprising: a ribozyme [which] that specifically cleaves a [TARP-encoding] nucleic acid of claim 10, an antisense oligonucleotide [which] that specifically binds to a [TARP-encoding] nucleic acid of claim 10, a DNA binding protein [which] that binds specifically to a [TARP-encoding] nucleic acid of claim 10, [and] or a nucleic acid of claim 10, [encoding TARP] operatively linked to a promoter.

Please add the following new claims:

- 45. (New) The substantially purified polypeptide of claim 1, wherein the polypeptide comprises the amino acid sequence set forth as SEQ ID NO: 14.
- 46. (New) The nucleic acid of claim 10, comprising the nucleic acid sequence as set forth as SEQ ID NO: 13.
  - 47. (New) A vector comprising the nucleic acid of claim 15.
- 48. (New) The method of claim 36, comprising detecting the hybridization in a prostate epithelial cell of a male.

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- 49. (New) The method of claim 36, comprising detecting the hybridization in a breast cell of a female.
- 50. (New) A method of detecting cancer in a subject, comprising detecting the contacting of an antibody that specifically binds a protein having the amino acid sequence as set forth as SEQ ID NO: 14, or a variant thereof having a conservative substitution in a sample from the subject, whereby detection of the binding indicates that the subject has cancer.
- 51. (New) The method of claim 36, wherein the subject is a male and the cell is a prostate epithelial cell.
- 52. (New) The method of claim 36, wherein the subject is a female and the cell is a breast cell.
  - 53. (New) The method of claim 51, wherein the sample comprises a lymph node cell.
- 54. (New) The method of claim 51, wherein the sample comprises a breast biopsy cell.